Author's response to reviews

Title: One stop or full stop? The continuing challenges for researchers despite the new streamlined NHS research governance process

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Author's response to reviews: see over
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Dear Dr Clark

We are pleased to be able to re-submit our manuscript for your consideration, taking into account the views of the four reviewers. We welcomed the various opinions on the paper, as it helped us to strengthen the arguments and hopefully make clearer the contribution we intended to make.

Please find appended below our responses to the various points that were raised by each reviewer in turn. These have been incorporated into the manuscript as indicated.

We submitted the Final Report to the SDO in mid-March and now have to wait for it to be peer-reviewed and any subsequent revisions to be made, prior to it being posted on their website. We would expect this will take a further four to six months. We would not be publishing the report on our website, but, rather, would post a link to the SDO website.

We are intrigued to know why you wish to have a copy of the questionnaire, since it has no relevance to this article. It will be available on the NIHR SDO website, as part of our Final Report, in due course. We are presuming that you are referring to the patient questionnaire used in this stage of the research project.

Many thanks for your guidance and prompt response to our submission. We look forward to hearing your decision in due course.

Yours sincerely,

Emma France (pp Andrew Thompson)
Reviewer: Hal Swerissen

Reviewer's report:

This is a case study of the efficiency of recently introduced changes to the NHS research governance process. The title is appropriate. The question is well defined but narrow. It focuses primarily on the time taken to complete research governance procedures for multisite research studies and the implications of the delays found. The methodology was suitable for the study. The case study found that that research governance approvals for the study investigated, took considerably longer in England than in Scotland, that there was considerable site variation in the time taken for approval and that primary care trusts took particularly lengthy periods for approval to be obtained. The study commented appropriately on the implications of variability and delays in governance decisions for the implementation of research projects.

The study comments somewhat speculatively on the reasons why this might be so, but without detailed investigation.

Whilst it is the case that we did not report it here, we made a number of attempts to ascertain the reasons for the delays. Perhaps it is of no surprise that, even where we had approvals, albeit rather late, we failed to receive any explanation for the delays, even where one manager said he would follow it up on our behalf. This may partly reflect the fact that there is no requirement for accountability to researchers seeking permission. We feel, therefore, that we cannot provide any evidence-based comment in the article.

It is worth noting this was a particularly extensive multisite research project and it was conducted early in the implementation of the new procedures. While the delays reported were significant and problematic, the authors need to more clearly address the question whether appropriate training and experience will result in appropriate predictability, timeliness and consistency or are the processes fundamentally flawed and in need of revision?

We think this is a very interesting and important question, which we have tried to grapple with. Our view, as expressed in the paper, was that part of the problem was undoubtedly the ill-preparedness of the new coordinating bodies for the revised system. After lengthy delays resulting from this, the processes did indeed move in the intended direction from the centre, but failed to move at the next levels in the hierarchy. It is our view, although we cannot provide strong evidence for it, that training and experience would not be sufficient to resolve the problem, since there appeared to be a lack of sufficient resources to provide staff training in the first place and there were also a number of organisational deadlocks regarding when action should take place. This may not necessarily require a root and branch overhaul of the system, but it does seem to need some fundamental issues of responsibility and accountability to be sorted out, supported by sufficient resources and investment in training and communication. We have reinforced this point with a new paragraph in the conclusion.

Further, the study does not comment on the quality of the data gathering or decision making procedures and the quality of the outcomes of decision making. Timeliness is
important, but it would be interesting to know whether the authors considered the quality of the decisions and advice they received useful or not.

Unless we have missed the point, we are not aware of any quality issues regarding data or outcomes for these decisions. All we were expecting from Primary Care Trusts, Acute Trusts, or Foundation Trusts (or Health Boards in Scotland) was a decision to allow or prohibit the use of the service providing organisation as a Patient Identification Centre (PIC). No further advice or information was expected, nor given. Where such advice might be useful would be at the next stage of recruiting lymphoma clinics or general practices, which we do not report on here.

The study is generally well written, but needs tight copy editing to remove the occasional error.

We have been through the article to find the errors, as well as asking colleagues to assist, but we have to be honest and say that all we could find were some possible under/over uses of hyphens. However, we are more than happy to deal with them if they could be indicated to us.

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I have no competing interests
Reviewer: Glyn Elwyn

Reviewer's report:
Discretionary review

Level of interest: An article of outstanding merit and interest in its field

We are grateful for this highly positive view of the merits of our article.

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests'
Reviewer: Leslie Gelling

Reviewer's report:
There are some interesting arguments in this paper but I also have some considerable concerns.

Major compulsory revisions:
1. This paper is written in an extremely negative tone which risks painting an inaccurate picture of the current process for research governance review in the NHS. The content may reflect the experiences of the authors but it does not necessarily accurately reflect the current situation. Whilst acknowledging that there are still problems with governance review, this paper is extremely critical whilst lacking a constructive approach to suggesting a way forward.

We acknowledge that there is a risk of misinterpretation or over-generalisation based on a single case study, which we have now made more explicit towards the end of the discussion. There is no doubt that we view the situation for obtaining RM&G approvals as unacceptable and hence have felt compelled to write this article as a rallying call for action. We feel that the judgement as to whether we have been unfairly critical will rest with the response it generates from other researchers in a similar position.

However, we find it difficult to support the idea that we have been excessively critical and unconstructive in our recommendations. We are not arguing for a complete rejection of the new system, but rather that the espoused benefits are far from being realised. Examples of positive comments have been made explicit in relation to a number of aspects which we feel deserve support and acknowledgement; e.g.
- having one REC act on behalf of all RECs
- having one coordinating centre for leading on approvals, irrespective of the nation of origin in the UK
- the new application system (IRAS), linking ethics and R&D approvals
- the software for completing the IRAS form
- the speed and efficiency of the ethics review
- the value of having RECs' reflections on the research process
- the time targets set for RECs and NHS providers to give permission.

Nonetheless, we have tried to improve on the recommendations we made by making them clearer with a new paragraph in the conclusion.

2. The main criticism in this paper is directed at research governance review and not at ethical review. This needs to be much clearer to the reader from the outset.

The reviewer is correct in saying that our main criticism is directed at the R&D aspect rather than the ethical review. We are not sure we can be any clearer than we have already been, as laid out in the abstract; viz.

“Our experience of the ethics stage was very positive, noting an efficient process of application and a speedy decision, both in relation to the initial application and to subsequent substantial amendments. By contrast, the R&D stages were very slow,
most with unexplained delays, but some offering contradictory advice and exhibiting a lack of clear guidance and training for NHS staff.”

However, in order to reinforce this point even more, we reiterate how positively we viewed the ethics stage at the end of the first paragraph in the results, to contrast with the existing first sentence in the paragraph that follows.

3. The content of this paper is not suited to the format in which it is presented. The structure of the paper is that traditionally used to present research findings but the content does not fit comfortably into this format. The arguments might be better presented as a discussion paper or editorial.

Following the advice of the editor, we have left this as a research document.

Minor essential revisions:
4. In the abstract the ‘ethical and R&D’ processes are described as ‘managerial layers’. It seems rather odd to describe these processes in this way. They may form part of the management of the research project but those involved in ethical or governance review will probably not consider their work ‘managerial’. The wording needs to be changed.

The intention was to relate it specifically to R&D, but we accept it looks as though it includes the ethical review. We have removed the word ‘managerial’ to avoid this confusion.

5. On page 3, sentence beginning ‘Ethical practice in research has long been assumed …’ needs some justification and I am not sure it is an accurate reflection of the public perception of research. It may be true that ethical (clinical) practice is an integral part of any code of practice but I need convincing that the public believes the same of practice in research. Clinical professions have repeatedly demonstrated that codes of practice have not prevented unethical research. It is surely a combination of the law (a more recent development) and independent ethical review that does this. I strongly recommend a revision of this wording.

We agree that this statement currently makes an insupportable contention, so we have changed it to indicate that there is likely to be a public expectation about the normative character of professional conduct; i.e. “Ethical practice in research can be reasonably expected by the public to be part and parcel of the normative professional code of conduct.” This allows for public outrage when ethical standards are not met, which is included in the next sentence as resulting from some notorious cases.

6. It is suggested that it should not be the role of research ethics committees to review the science of applications. This statement demonstrates some lack of understanding of what research ethics committees do. If an application has been through a thorough peer review process, such as the research councils, then the REC will not focus on the science. It remains the case that many applications have still had no review of the science, or an inadequate review, and this is when the REC has no option but to consider the science … ‘bad science is bad ethics’.
While we can accept that not all RECs review the science of a study, it is our experience and the experience of others whom we know that questions are often raised that are of a scientific nature, even when the research proposal has been through recognised peer review; e.g. questions about the sampling design. As David Hunter makes clear\(^1\), based on the Department of Health’s guidance, RECs are not supposed to judge the scientific quality of a study, but solely the ethical aspects. As he argues, poor science is not necessarily unethical; otherwise we would be in a position where all research is unethical since improvements are continually being made to its conduct as we acquire knowledge about its process. We have, therefore, amended our sentence to refer to what is more broadly known as ‘ethics creep’.

7. I need convincing that deficiencies in the current review processes will inevitably result in poorer research outputs (see final paragraph of the conclusion). It seems odd that the quality of a research output can be anything other than the author’s responsibility.

While it would be wrong to blame external factors for the failings of researchers, equally, it seems to us, researchers cannot be held to account for external factors over which they have no control but to which they are obliged to conform. Our final paragraph lists the consequences of an inability to secure approval to sample in NHS organisations, despite the strengths of the research design. In our case we were stymied from managing to secure any respondents at all from primary care in England and had to accept a much reduced sample of lymphoma patients too. Thus, our conclusion emphasises the resulting loss of power in analysis, the probable unrepresentative resulting sample, the fact that we could not say anything about some of the conditions of interest, the time wasted in progress chasing, often to no avail, and the final effect on value for money. We might have done things better, but the odds of getting a more propitious outcome were surely stacked against us as a result of the R&D process. For these reasons we find it difficult to be more positive than we have been.

Discretionary revisions:
None.

Throughout the paper there does need to be more balanced arguments and less of a critical attack of the current review processes.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.

Reviewer: Rosie Kneafsey

Reviewer's report:
The article comprises a well written descriptive case study of a research teams’ experience of seeking Research Governance and Management approval for a survey based study in the UK.

It provides a useful window into the experiences of active and experienced researchers, which unfortunately, was largely negative. It highlights the damaging impact of the apparently unwieldy system of research monitoring which will surely resonate with researchers across the UK. As such, for UK based researchers, the paper will be of interest.

However, for members of the international community, the number of acronyms and different groups and committees referred to in the paper may prove to be off-putting. It might be worthwhile the authors writing out some of the acronyms in full to add greater clarity – or perhaps a glossary of terms.

We agree that the proliferation of acronyms can be very off-putting. Whilst we feel we did spell them all out in the text (apart from R&D, NHS and IT), we have compiled a glossary as a helpful additional resource.

In addition, some readers may be unclear regarding what is meant by the ‘constituent nations of the UK’ (p1). This could be clarified on the first page.

We have clarified this as follows in the abstract: “…the constituent nations of the UK (England, Scotland, Wales and Northern Ireland)…”.

Also, I was not sure what was meant by the term ‘domiciliary interviews’.

We have removed the term ‘domiciliary interviews’ and rephrased the sentence to start as follows: “The method involved home-based, face-to-face interviewing…”.

The international relevance of the paper could perhaps be strengthened if the authors were able to make some wider comparisons with the literature on Research Governance emanating from America or other European/Scandinavian Nations for example.

We have added in examples from other developed countries: “Similar developments are taking place elsewhere in the world, at a varying pace, but in the same direction, with related concerns about the efficacy of the governance arrangements. There are major differences between European countries as to what needs to be submitted to Research Ethics Committees (RECs), with the UK being noted as having an arduous process [11]. In the USA federal policies on human subjects research has become strongly protectionist [12], with increased strictures on governing research by the Institutional Review Boards [13]. Problems in the under-resourcing and overworking, not to mention the lack of clear accountability structures, of Human Research Ethics Committees in Australia [14] and Research Ethics Boards in Canada [15], have led to demands to reform their governance systems.”
The authors could add to the evidence base relating to the implementation of Research Governance by suggesting some solutions to the apparent lack of accountability of those organisations involved in the application of the RG&M processes.

We have expanded on the problems we identified in the conclusion to suggest possible solutions as recommended: “We would support the recommendation of Appleton and colleagues [30] that a collaborative framework be set up that brings together researchers and those vested with responsibility for designing and implementing research governance processes, extending it to cover the whole of the NHS. A clear communications strategy needs to be in place to ensure all parts of the system are in harmony and understand what is required, supported by properly financed training and IT systems. Despite the difficulties of dealing with the many variables at play, there needs to be a limit on the time taken by any part of the system, especially CLRNs, to approve or disapprove a research project taking place, and, in the case of the latter decision, with clear explanations as to why it has failed. An interesting question for the NIHR to answer would be the opportunity cost of research projects that have been abandoned or reduced in scope as a result of failures in the RM&G approvals process for reasons other than poor science.”.

Whilst readers of the article will recognise it’s value, the authors should make a short note justifying the usefulness of a descriptive piece such as this, but also recognise the limitations of a single case study as a means of generalising more widely.

We agree that we should have been more explicit in the limitations of this case study, which we have added to the end of the discussion; i.e.

“The narrative we have presented in this case study offers a detailed description of the difficult journey that faces investigators attempting to sample within the NHS in England, in particular, and to a much lesser extent in Scotland. A limitation of this study is that, being a single case, it may not be generalisable to the experiences of other researchers. However, many of the problems we faced at the level of service provider were not new and, even if some of them were teething problems in the new arrangements, there are still worrying examples of lack of forethought, resources and management in the implementation stage, which will require deliberate action to resolve.”

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.